

REMARKS

Reconsideration of this Application is respectfully requested. Applicants thank the Examiner for the withdrawal of those rejections of record in the previous Official Action, mailed February 13, 2004, that are not mentioned in the current action.

Upon entry of the foregoing Amendment, claims 1-18, 20, and 21 are pending in the Application, with claims 19 and 22-31 having been cancelled. The Amendment accompanying this response is believed to introduce no new matter and its entry is respectfully requested. Support for the amendments is found throughout the specification and claims as filed. Claim 5 has been amended to remove matter directed to non-elected SEQ ID NO:2 and to correspond with the restriction requirement mailed on December 17, 2002. Based on the Amendment and the following remarks, applicants submit that all rejections have been overcome and that the Application is in condition for allowance. Applicants respectfully request that the Examiner reconsider all outstanding rejections and that they be withdrawn and the pending claims allowed.

The Examiner has rejected claim 5 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Applicants respectfully traverse. It is well-established that a determination of whether an invention is enabled rests on whether the experimentation necessary to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Furthermore, the fact that experimentation may be complex does not make it undue, so long as those in the art typically engage in such experimentation. *In re Certain Limited-Charge Cell*

Culture Microcarriers, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd sub nom.*, *Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985).

Applicants submit that, as set forth below, one skilled at the art would have been able to construct the claimed vectors with the guidance of the specification and without undue or unreasonable experimentation. It is to be understood that Applicants' explanation of steps used to make the vectors claimed herein should not be construed to be the only way that such vectors may be made; instead, this description is only one of many possibilities that may be contemplated in the specification.

Example 3 discusses construction of a *Candida famata* gene library using the plasmid p19L2, which was in turn constructed from the commercially available *S. cerevisiae* plasmid Yep19. This library was used in the construction of vectors pCfARS6, pCfARS11, and pCfARS16, as set forth in Example 6 of the specification. Example 6 includes detailed restriction analysis of these vectors. Furthermore, the linear schemes of these vectors are set forth in Figures 6, 7, and 11. The nucleotide sequence of pCfARS16 (SEQ ID NO: 3) is set forth in Figure 20.

Example 14 sets forth derivation and construction of vector pCfARS1614 from pCfARS16. Example 14 further describes the construction of pCfARS62 from pCfARS6, and the construction of pCfARS68 from pCfARS62. To further aid construction of these vectors, the linear sequence of pCfARS1614 is shown in Figure 2, and the linear sequence of pCfARS62 is shown in Figure 11.

Example 18 sets forth construction of vector pRIV-1 by transformation of the cells of mutant 5-109 using plasmid DNA containing the gene library of *C. famata* VKM Y-9 on

pCfARS1614. This resulted in the creation of the Leu^+Rib^+ transformant pRIV-1. Use of pRIV-1 is further described in Example 21, and electrophoresis of pRIV-1 is shown in Figure 12. Vector pRIV-1 is used, in turn, in the construction of pRpRIV-1 and pRIV-2, as described in Example 21. The linear sequence of pRIV-2 is shown in Figure 17.

Vector pCR7, isolated from a transformed $\text{leu2}^-\text{rib7}^-$ mutant, is shown in linear form in Figure 19, and an extensive restriction analysis is set forth in Example 26. Vector pCR1, which is the pCfARS1614 vector with a ~3kb insert, was obtained as described in Example 26. Vector pCR1 was further used (with an incorporated PgARS element as shown in SEQ ID NO: 2) to create vector PRp1. After PRp1 and pCR7 were constructed, they were used to construct vectors pCR1Xb and PRp1Xb, as set forth in Example 28. The linear sequences for pCR1Xb and PRp1Xb are set forth, respectively, in Figure 23 and Figure 24.

Isolation of vector pCR2 is described in Example 31, wherein pCR2 is characterized as comprising the pCfARS1614 (the construction of which is described above) vector with an insert of about 6.4kb. Figure 25 sets forth the linear sequence of pCR2. Example 31 further describes the construction and use of pCR2-1, which may be made by treating pCR2 with nuclease XbaI and allowing self-ligation. Addition of further XbaI fragments yields pCR2-21 and pCR2-22. Figure 28 sets forth the linear sequences of pCR2, pCR2-1, pCR2-21, and pCR2-22.

Example 31 further describes the construction of vectors PRp2-11 and PRp2-12 by insertion of an ARS from *P. guilliermondii* into a pCR1 plasmid. Both of these vectors are based on pCfARS1614, and their linear sequences are shown in Figure 29.

Vector PRpIV-2 is a derivative of pRIV-2, and its linear sequence is shown in Figure 31. As described in Example 35, PRpIV-2 was constructed by insertion of a PgARS element into a pRIV-2 vector. As further set forth in Example 35, vectors p19R7RIV-21 and p19R7RIV-22 are

recombinant plasmids constructed by subcloning PRpIV-2 using p19R7R1. Their linear sequences are set forth in Figure 33.

The components of vector pCPR5 are described in Example 37 and are set forth in linear form in Figure 38. Vector pCPSR5 is a derivative of pCPR5; its components are described in Example 43, and its linear sequence is set forth in Figure 42. The structures of pFC and pFCL-2 are described in Example 37, and their linear sequences are set forth in Figure 39.

Vector PRp7 is described in Example 26 as a pCR7 plasmid that includes a PgARS insert. The linear scheme of vector PRp7 is shown in Figure 19. Vectors PRSp1Xb, PRSp7, pFCLS2, and PRSp2-11 are discussed in Example 43, and their linear schemes are shown in Figures 40-45. As described and shown, these vectors include replication sequences from four hosts, including *C. famata*.

Vector pRIB7 is derived from pCfARS1614 and is described in Example 46. Vector p2R is described in Example 40 as containing "the selective marker LEU2 gene of *S. cerevisiae*, PgARS, CfARS and the complete sequence of the bacterial vector pUC 19." The linear scheme of p2R is shown in Figure 26. Example 46 describes the construction of pR15 from pPR5 and pCR1Xb. Vector pR15 was further used in conjunction with the *C. famata* RIB7 gene to construct vector pR157, which was, in turn, used to create pR1572 as further described in Example 46. Example 46 also describes vectors pR2 and pRIB1, both of which are pCfARS1614 derivatives.

The Examiner has rejected claims 6-12 as allegedly indefinite under 35 U.S.C. § 112, second paragraph. Applicants respectfully submit that the amendments included herein render the rejection of those claims moot. Withdrawal of the rejection and allowance of the claims is respectfully requested.

CONCLUSION

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and as such, the present Application is in condition for allowance. If the Examiner believes for any reason that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "Duane A. Stewart III". The signature is fluid and cursive, with a large, stylized "S" at the end.

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Duane A. Stewart III
Registration No. 54,468
BUCHANAN INGERSOLL PC
One Oxford Centre
301 Grant Street
Pittsburgh, Pennsylvania 15219
ph: (412) 562-1622
fx: (412) 562-1041